



**DIVISION OF CONSOLIDATED LABORATORY SERVICES**

**PROTOCOL FOR LABORATORIES SEEKING CERTIFICATION TO PERFORM  
MICROBIOLOGICAL AND CHEMICAL ANALYSIS OF DRINKING WATER UNDER  
THE SAFE DRINKING WATER PROGRAM**

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## **PROTOCOL FOR LABORATORIES SEEKING CERTIFICATION TO PERFORM MICROBIOLOGICAL AND CHEMICAL ANALYSIS OF DRINKING WATER UNDER THE SAFE DRINKING WATER PROGRAM**

### **1. SCOPE and PURPOSE**

- 1.1 The purpose of this protocol is to describe the criteria for laboratories performing microbiological and chemical analysis of drinking water to obtain certification under Title 1, Agency 30, Chapter 40, Sections 10 through 370, of the Virginia Administrative Code (1VAC30-40).
- 1.2 This document describes the Division of Consolidated Laboratory Services (DCLS) protocols for the utilization of proficiency testing studies and on-site laboratory assessments to certify, continue certification, and re-certify in-state and out-of-state laboratories under the provisions of the Safe Drinking Water Act (SDWA). It applies to all laboratories seeking certification in Virginia under 1VAC30-40 for the analysis of drinking water.
- 1.3 The Drinking Water and Tuning Fork Laboratory Certification Group serves the following customers:
  - Virginia Department of Health, Office of Drinking Water
  - Non-commercial analytical laboratories attached to public water supply utilities located in Virginia.
  - Commercial laboratories located in Virginia that provide analytical services to public utilities as well as private customers.
  - Commercial and non-commercial laboratories located outside of Virginia who have been granted reciprocal certification to provide analytical services to customers located in Virginia.
  - Private citizens who wish to employ the services of a certified laboratory for the testing of drinking water from private sources.

### **2. DEFINITIONS**

- 2.1 See 1VAC30-40-20 for definitions associated with the certification program.
- 2.2 See *USEPA Manual for the Certification of Laboratories Analyzing Drinking Water, 5<sup>th</sup> Edition, and associated Supplement(s)* for definitions associated with program requirements. Such definitions include Types of Certification, as follows:
  - 2.2.1 Certified: a laboratory that meets the regulatory performance criteria as explained in this manual and all other applicable regulatory requirements.
  - 2.2.2 Provisionally Certified: a laboratory that has deficiencies but demonstrates its ability to consistently produce valid data within acceptance limits specified in the National Primary Drinking Water Regulations, and within the policy required by their certification authority. A provisionally certified laboratory may analyze drinking water samples for

compliance purposes, if the said clients are notified of its downgraded status in writing, on any report. Provisional certification may not be given if the evaluation team believes that the laboratory cannot perform an analysis within the acceptance limits specified in the regulations. Provisional certification generally does not exceed three months.

- 2.2.3 Not Certified: a laboratory that possesses deficiencies and, in the opinion of the Certification Authority, cannot consistently produce valid data.
- 2.2.4 Interim Certification: interim certification may be granted in certain circumstances when it is impossible or unnecessary to perform an on-site audit. Interim certification status may be granted if, for example, the Certification Authority (CA) determines that the laboratory has the appropriate instrumentation, is using the approved methods, has adequately trained personnel to perform the analyses, and has satisfactorily analyzed PT samples, if available, for the contaminants in question. The Certification Officer (CO) should perform an on-site audit as soon as possible but no later than three years. An example of a situation where this type of certification is warranted would be a laboratory that has requested certification for the analysis of additional analytes that involve a method for which it already has certification. The CO should review the laboratory's quality control data before granting this type of certification.

### 3. **RELATED DOCUMENTS**

- 3.1 Documentation regarding other DCLS policies on drinking water laboratory certification is available upon request from the certification office.
- 3.2 §2.2-1102 and §2.2-1105 of the Code of Virginia and 1VAC30-40 are the statutory and regulatory basis for the Safe Drinking Water Laboratory Certification program in Virginia.
- 3.3 1VAC30-40 incorporates by reference the sampling, analytical methodology, and laboratory certification requirements of 40 CFR 141 and 143.
- 3.4 1VAC30-40, accessible by chapter, can be found at <http://leg1.state.va.us>.
- 3.5 *USEPA Manual for the Certification of Laboratories Analyzing Drinking Water, 5<sup>th</sup> Edition, 5<sup>th</sup> Edition, EPA 815-R-05-004, January 2005, and associated Supplement(s).*

### 4. **REQUIREMENTS FOR INITIAL CERTIFICATION**

- 4.1 Initial Application - Requests for certification will be made to DCLS by submitting a completed application (Form DGS-21-109), all relevant requested materials, and fee payment. The application packet is available at [www.dgs.virginia.gov/dcls](http://www.dgs.virginia.gov/dcls) (click on Drinking Water Certification) or by contacting the DCLS Laboratory Certification office.
- 4.2 The applicant laboratory will submit a Quality Assurance Plan with the application. Detailed descriptions of the required contents of the QA Plan are outlined in Chapter III, Section 11 of the *USEPA Manual for the Certification of Laboratories Analyzing Drinking Water, 5<sup>th</sup> Edition*.
- 4.2.1 If the laboratory is applying for certification for microbiological testing methods, then it will submit sampling information and test results for at least twenty analyses for each

method. Sampling information is outlined in the EPA *Manual*, Chapter V, Section 6.5 and 8.3, and test results are outlined in the EPA *Manual*, Chapter V, Section 8.4.

- 4.2.2 If the laboratory is applying for certification for chemistry methods, then it will submit documentation of the initial demonstration of capability (IDC) and Method Detection Limit (MDL) for each method and parameter in accordance with the EPA *Manual*, Chapter IV, Sections 7.2.9 and 7.2.11. Documentation of Minimum Detectable Activity (MDA) is submitted in lieu of MDLs for radiochemical analyses.
- 4.3 The laboratory will also submit a satisfactory report of at least one proficiency test (PT) for each method and parameter for which the laboratory seeks certification. The PT must have been analyzed within 12 months of the application date.
- 4.4 The laboratory must submit applicable fees for certification, as described in Section 6 of this procedure.

## 5. APPLICATION REVIEW

- 5.1 The application and the QA Plan will be reviewed by the DCLS Certification Officer. Based on the review of the application, one of the following actions will be initiated within 60 days of the receipt of the application:
- 5.1.1 The Certification Officer will reply to the laboratory with a letter identifying the additional information or other requirements needed to satisfy the application process and give the laboratory 90 days to respond.
- 5.1.2 The Certification Officer will contact the laboratory by telephone or email to get clarification of minor problems. The Certification Officer will initial and date the changes in the application mutually agreed upon with the laboratory.
- 5.1.3 The application is accepted as complete. The Certification Officer will contact the laboratory and schedule a mutually agreeable date for an on-site inspection.

## 6. FEE

- 6.1 Fees are currently waived for state, local, and federal government laboratories.
- 6.2 Commercial laboratories must pay an application fee for each category for which certification is being requested, payable to the Treasurer of Virginia. The fee must accompany the application packet and is non-refundable. The laboratory will mail the application and check to: Attn.: Drinking Water Laboratory Certification, 600 N 5<sup>th</sup> St., Richmond, Virginia 23219.
- 6.3 The certification categories and corresponding fees are as follows:

<u>Categories</u>	<u>Fees</u>
Microbiology	
• 1-2 methods	\$ 600
• 3-5 methods	\$ 700
• 6 or more methods	\$ 800
Inorganic Chemistry / Metals	

- 1-2 methods                      \$1000
- 3-5 methods                      \$1250
- 6 or more methods              \$1400

Inorganic Chemistry / Non-Metals

- 1-2 methods                      \$ 650
- 3-5 methods                      \$ 850
- 6-8 methods                      \$1050
- 9 or more methods              \$1250

Organic Chemistry

- 1-2 methods                      \$1050
- 3-5 methods                      \$1250
- 6-8 methods                      \$1450
- 9 or more methods              \$1650

Radiochemistry

- 1-2 methods                      \$1100
- 3-5 methods                      \$1300
- 6 or more methods              \$1500

Asbestos

- 1-2 methods                      \$ 900
- 3-5 methods                      \$1100
- 6 or more methods              \$1300

6.4 A certification renewal fee is payable every year for each category for which certification has been granted. It is not prorated.

6.5 Additional fees:

6.5.1 An additional fee shall be charged:

6.5.1.1 To laboratories applying for modification to certification.

6.5.1.2 To laboratories that move their location when the move requires DCLS to perform an on-site assessment.

6.5.1.3 To laboratories requesting reinstatement of certification when DCLS requires an on-site assessment.

6.5.2 The fee charged shall be the sum of the total hourly charges for all reviewers plus any on-site assessment costs incurred. An hourly charge per reviewer shall be determined by (i) obtaining a yearly cost by multiplying the reviewer's annual salary by 1.35 (accounts for overhead such as taxes and insurance) and then (ii) dividing the yearly cost by 1,642 (number of annual hours established by Fiscal Services, DGS, for billing purposes). The charge per reviewer shall be determined by multiplying the number of hours expended in the review by the reviewer's hourly charge. If an on-site review is required, travel time and on-site review time shall be charged at the same hourly charge per reviewer, and any travel expenses shall be added.

## **7      ON-SITE INSPECTION AND REPORT**

7.1      Upon receipt of a complete application, the Certification Officer will schedule the on-site inspection at a mutually agreeable date, generally within 90 days and with three weeks advance notice. The on-site assessment includes a review of:

- laboratory personnel qualifications and training,
- operations,
- equipment,
- supplies,
- general laboratory practices,
- sample handling procedures,
- methodology,
- written procedures, and
- laboratory records.

Chemistry and microbiology personnel will be interviewed in their work areas. Laboratory personnel will also be asked to demonstrate drinking water microbiology methods during each on-site inspection.

7.2      Within 30 days of the on-site inspection a comprehensive report will be prepared by the DCLS Certification Officer. The inspection report will document any deficiencies and offer recommendations. Upon receipt of the report, the laboratory seeking certification has 60 days to submit to DCLS a corrective action plan addressing the deficiencies cited in the report.

7.3      An on-site inspection will be conducted at each laboratory at least once every three years. DCLS reserves the right to perform interim announced and unannounced inspections. If on-site inspections are refused, DCLS may revoke certification.

## **8.      CERTIFICATE**

8.1      A certificate is issued annually. The certification period is July 1 through June 30.

8.2      A certificate is accompanied by an Annual Certified Parameter List (ACPL) which details the specific analyte/method combinations for which the laboratory is certified.

## **9.      MAINTENANCE OF CERTIFICATION**

9.1      The laboratory must notify DCLS within thirty (30) days of changes in personnel, procedures, equipment or laboratory location. The DCLS Certification Officer will acknowledge receipt of the change notification by email or phone generally within one week of receipt.

9.2      To maintain certification, the laboratory must continue to meet the requirements listed in the *Regulations for the Certification of Laboratories Analyzing Drinking Water* and the requirements listed in 1VAC30-40.

**10. RENEWAL OF CERTIFICATION**

- 10.1 Renewal invoices will be sent out to commercial laboratories approximately three months before the expiration of the certificate.
- 10.2 Payment is due one month before the certificate expiration date. Failure to remit payment on time may delay re-certification and may result in revocation of certification.

**11. PROFICIENCY TESTING (PT) STUDIES**

- 11.1 The chemistry and microbiology Water Supply (WS) PT samples used for certification compliance must be purchased from providers who have been approved by the American Association for Laboratory Accreditation utilizing the “National Standards for Water Proficiency Testing Studies”.
- 11.2 It is the responsibility of the individual laboratories seeking or maintaining certification to initiate the purchase and analysis of PT samples. The individual laboratories are to instruct the PT providers to submit copies of all results to the Laboratory Certification Office at DCLS, 600 North 5<sup>th</sup> Street, Richmond, VA 23219.
- 11.3 Laboratories located in Virginia are responsible for analyzing and completing PT Studies on a calendar year (January- December) basis within acceptance limits established by the approved PT provider for all certifiable contaminants by each method for which the laboratory seeks certification. Laboratories located outside of Virginia perform PT studies according to the schedule of their accrediting agency.
- 11.4 DCLS requires laboratories to perform PT studies prior to September 30 of each year. This allows laboratories which fail a study enough time to perform and document corrective action as well as perform a makeup PT study prior to December 31.
- 11.5 For a failed PT, the laboratory shall perform and document corrective action. The corrective action documentation shall be submitted to DCLS within 30 days of the “not acceptable” PT result.
- 11.6 Certification status will be evaluated by the laboratory certification officer against the laboratory’s annual PT performance. It is the laboratory’s responsibility to assure that at least one “acceptable” PT result was achieved in a calendar year for all certified chemical and microbiological parameters by each method/analyte for which the laboratory seeks certification.
- 11.7 The certification status for all parameters for which “acceptable” results were reported will be established as or maintained as “certified”.
- 11.8 The certification status for any parameters for which the laboratory has not achieved “acceptable” results during the calendar year, whether due to non-participation or “not acceptable” PT results for two successive PT studies, will be downgraded to “provisionally certified.” [See 12.1.2 for restrictions placed on provisionally certified laboratories.]



- 11.9 Following submission of a corrective action plan for the failed make-up PT study and documentation of successful implementation, the laboratory may enroll in a second makeup PT study.
- 11.10 Successful participation in this study will restore the certification status from “provisionally certified” to “certified”.
- 11.11 Unsuccessful participation in this study will cause the certification status to be downgraded from “provisionally certified” to “not certified.” [See 12.2.2 for restrictions placed on “not certified” laboratories.]
- 11.12 A parameter may not be listed as “provisionally certified” for more than 3 months. If the laboratory has not restored a “provisionally certified” parameter to “certified” within three months of the downgraded status, the parameter will be fully downgraded to “not certified”.
- 11.13 Three successive failures for PT study will result in the laboratory certification to be downgraded to “not certified”.
- 11.14 Following loss of certification for a parameter, the laboratory must do the following in order to restore the certification status to “certified”:
- perform and submit documentation of corrective action to DCLS.
  - perform a successful PT study.
  - request, in writing, that the certification be restored.
  - pay applicable fees associated with restoration.
- Once DCLS reviews the corrective action, supporting documentation, and any related data requests made by DCLS, the laboratory may participate in a PT study. Successful participation in this PT study will restore the PT status to certified.
- 11.15 A PT Study performed to demonstrate successful Corrective Action from a failed PT study in the previous calendar year does not satisfy the requirement for an annual PT study in that calendar year. Example: A makeup PT study performed in January 2011 for a failed study in November 2010 does not meet the calendar year PT requirement for 2011. Another PT must be performed in 2011.
- 11.16 The PT records will be maintained by the Certification Officer as part of the State SDWA Program files. Files for each laboratory will be maintained containing the last 7 calendar years of PT performance.
- 11.17 PT records are filed by laboratory name and year and consist of PT provider reports for the PT studies, the annual certified parameter list, and the corrective action reports from in-state laboratories.
- 11.18 PT performance records produced from the DCLS Laboratory Certification database are the principal PT tracking tool.
- 11.19 Reciprocal laboratories are not required to submit PT reports to Virginia. Their proficiency test performance is tracked by their primary accrediting authorities.

## 12. **CHANGE IN CERTIFICATION STATUS**

12.1 When the certification status is downgraded to “provisionally certified”:

- 12.1.1 DCLS will notify the laboratory by certified mail within 14 days of becoming aware of the need to downgrade the certification status.
- 12.1.2 A provisionally certified laboratory may continue to analyze samples for compliance purposes, but shall notify its clients of its downgraded status and provide that information, in writing, on any report.
- 12.1.3 The Certification Officer will notify by email the Virginia Department of Health Office of Drinking Water (VDH ODW) Central Office of the laboratory’s change in status.
- 12.1.4 DCLS will revise and re-issue the laboratory’s Annual Certified Parameter List.
- 12.1.5 If the issue causing the laboratory’s certification status to be downgraded to “provisionally certified” is not resolved within three months, the laboratory’s certification status will be fully downgraded to “not certified”.

12.2 When the certification status is downgraded to “not certified”:

- 12.2.1 DCLS will notify the laboratory by certified mail within 14 days of becoming aware of the need to downgrade the certification status.
- 12.2.2 Under this circumstance, the laboratory must stop analyzing SDWA compliance samples for the analytes/methods in question and send the samples to a laboratory that is certified to perform the analyses.
- 12.2.3 The Certification Officer will notify by email the Virginia Department of Health Office of Drinking Water (VDH ODW) Central Office of the laboratory’s change in status.
- 12.2.4 DCLS will revise and re-issue (if appropriate) the laboratory’s Annual Certified Parameter List.

12.3 When the certification status is restored to “certified”:

- 12.3.1 DCLS will revise and re-issue the laboratory’s Annual Certified Parameter List.
- 12.3.2 The Certification Officer will notify by email the Virginia Department of Health Office of Drinking Water (VDH ODW) Central Office of the laboratory’s change in status.

12.4 When the certification status is assigned as “interim”:

- 12.4.1 DCLS will grant “interim certification” when a laboratory cannot be site visited for the addition of a new parameter but the laboratory has met the requirements of the EPA Manual’s definition of “Interim Certification”.
- 12.4.2 A laboratory with interim certification may report data for compliance purposes.
- 12.4.3 The laboratory’s interim certification remains in effect until the site visit has been completed.

**13. LABORATORY'S REQUEST FOR CHANGE TO ANNUAL CERTIFIED  
PARAMETER LIST (ACPL)**

13.1 To request an addition of contaminants or methods to its certification, the drinking water laboratory shall submit the following to DCLS:

- 13.1.1 A completed DCLS drinking water certification application form.
- 13.1.2 An acceptable PT report for each requested method and contaminant, performed in the last 12 months.
- 13.1.3 The standard operating procedure for the requested method.
- 13.1.4 The current quality assurance plan, if requested.
- 13.1.5 For chemistry:
  - Method Detection Limit (MDL) documentation for each requested method and contaminant for which the laboratory seeks certification. (For radiochemistry, the Minimum Detectable Activity (MDA) documentation is submitted.)
  - Initial Demonstration of Capability (IDC) documentation for each requested method and contaminant for which the laboratory seeks certification.
- 13.1.6 For microbiology:
  - Sampling information and test results for at least 20 analyses by the requested method and contaminant combination.
- 13.1.7 An additional data packet, if requested.
- 13.2 DCLS will process a laboratory's request for additional contaminants and methods as quickly as possible, generally within 60 days of receipt. DCLS will make a determination regarding the requirement for a site visit prior to granting certification based on the similarity of the request for additional testing to the laboratory's current method list, the laboratory's demonstrated regulatory compliance, and the laboratory's proficiency testing history.
- 13.3 DCLS may grant interim certification status for the added contaminant(s) until such time that a site visit can be done, if the laboratory's request for additional contaminant(s) demonstrates that the laboratory has met the requirements of the definition of Interim Certification.

**14. RECIPROCAL CERTIFICATION**

- 14.1 Out-of-state laboratories applying for reciprocal certification must provide the following:
  - 14.1.1 A statement indicating the laboratory's need to serve customers in Virginia.
  - 14.1.2 A copy of the certificate and scope of certification issued by the laboratory's primary accrediting authority (NELAC, EPA, state, etc.).
  - 14.1.3 A list of method/analyte pairs for which the laboratory is requesting certification.
  - 14.1.4 The required fee for the certification category(ies) for which the laboratory is

seeking certification.

## **15. PROGRAM ADMINISTRATIVE TIMELINE**

The administration of the SDWA Program by DCLS staff follows this annual timeline of key events:

### **15.1 JANUARY**

- Announce the on-site inspections due in the calendar year to certified laboratories.
- January 1<sup>st</sup>: Start of Period for PT Testing for annual compliance.

### **15.2 APRIL**

- Mail renewal invoice to certified laboratories.

### **15.3 MAY - JUNE**

- Receive notices of fee payment from Fiscal Services.
- Document receipt of payment.
- Prepare certificates, annual certified parameter lists (ACPLS), and cover letters (generally done as payments are received).
- Submit certificates and ACPLs to Laboratory Director for signature.

### **15.4 JUNE - JULY**

- Contact laboratories that have not remitted fees to verify their intentions.

### **15.5 JULY**

- Send notice to any withdrawn or non-paying laboratories that they have been re-classified as "Not Certified"
- Provide an updated list of certified laboratories to the DCLS website and to the Office of Drinking Water.

### **15.6 SEPTEMBER**

- September 30<sup>th</sup>: End of Period for PT Testing for annual compliance.

### **15.7 SEPTEMBER - OCTOBER**

- Review PT histories for all Virginia labs and provide courtesy contact, if possible, to notify a laboratory that PT requirements have not been met. This is a courtesy to laboratories and not a responsibility of DCLS. The laboratory is responsible for meeting its certification requirements without reminders from DCLS.

### **15.8 DECEMBER - JANUARY**

- Follow-up to verify that laboratories met their PT requirements in the final quarter of the calendar year.
- Downgrade the accreditation status of any laboratory not satisfying the annual PT requirement by December 31<sup>st</sup>.

### **15.9 ONGOING RESPONSIBILITIES**

- Record PT data for Virginia labs in the DCLS database.
- Correspond with laboratories regarding corrective action for failed PTs.
- Correspond with ODW regarding changes in laboratory certification status.
- Update lists of certified laboratories on the DCLS website and with ODW as needed on a periodic basis to assure the information represented is current.

## **16. PUBLISHED INFORMATION**

- 16.1 A list describing the certification status of each laboratory is periodically posted at [www.dgs.virginia.gov/DCLS](http://www.dgs.virginia.gov/DCLS).

## **REFERENCES AND ASSOCIATED DOCUMENTS**

1VAC30-40, Regulations for the Certification of Laboratories Analyzing Drinking Water

*Manual for the Certification of Laboratories Analyzing Drinking Water: Criteria and Procedures, Quality Assurance*, 5<sup>th</sup> Edition, EPA 815-R-05-004, January 2005

DGS-21-209 SDWA Application (available from the DCLS Laboratory Certification Office with associated forms)

SDWA Inspection Checklists: See *Manual for the Certification of Laboratories Analyzing Drinking Water: Criteria and Procedures, Quality Assurance*, 5<sup>th</sup> Edition, EPA 815-R-05-004, January 2005